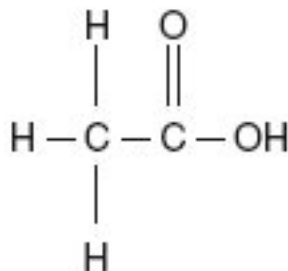


## HYDROCORTISONE AND ACETIC ACID - acetic acid and hydrocortisone solution

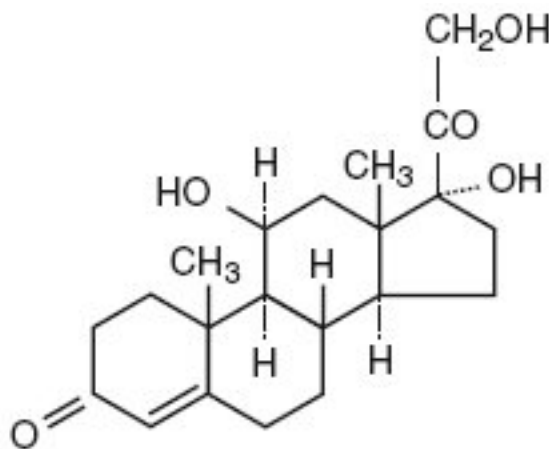
Qualitest Pharmaceuticals

### DESCRIPTION

Hydrocortisone and Acetic Acid Otic Solution, USP is a solution containing hydrocortisone (1%) and acetic acid (2%), in a propylene glycol vehicle containing propylene glycol diacetate (3%), benzethonium chloride (0.02%), sodium acetate (0.015%) and citric acid. The empirical formulas for acetic acid and hydrocortisone are  $\text{CH}_3\text{COOH}$  and  $\text{C}_{21}\text{H}_{30}\text{O}_5$ , with a molecular weight of 60.05 and 362.46, respectively. The structural formulas are:



Acetic Acid



Chemically, hydrocortisone is:  
Pregn-4-ene-3,20-dione,  
11, 17, 21-trihydroxy-, (11 $\beta$ )-.

Hydrocortisone and Acetic Acid Otic Solution is available as a nonaqueous otic solution buffered at pH 3 for use in the external ear canal.

### CLINICAL PHARMACOLOGY

Acetic acid is antibacterial and antifungal; hydrocortisone is anti-inflammatory, antiallergic and antipruritic; propylene glycol is hydrophilic and provides a low surface tension; benzethonium chloride is a surface active agent that promotes contact of the solution with tissues.

### INDICATIONS AND USAGE

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the antimicrobial, complicated by inflammation.

### CONTRAINDICATIONS

Hypersensitivity to Hydrocortisone and Acetic Acid Otic Solution or any of the ingredients; herpes simplex, vaccinia and varicella. Perforated tympanic membrane is considered a contraindication to the use of any medication in the external ear canal.

### WARNINGS

Discontinue promptly if sensitization or irritation occurs.

### PRECAUTIONS

Transient stinging or burning may be noted occasionally when the solution is first instilled into the acutely inflamed ear.

### PEDIATRIC USE

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

### ADVERSE REACTIONS

Stinging or burning may be noted occasionally; local irritation has occurred very rarely.

### DOSAGE AND ADMINISTRATION

Carefully remove all cerumen and debris to allow Hydrocortisone and Acetic Acid Otic Solution to contact infected surfaces directly. To promote continuous contact, insert a wick of cotton saturated with Hydrocortisone and Acetic Acid Otic Solution into the ear canal; the wick may also be saturated after insertion. Instruct the patient to keep the wick in for at least 24 hours and to keep it moist

by adding 3 to 5 drops of Hydrocortisone and Acetic Acid Otic Solution every 4 to 6 hours. The wick may be removed after 24 hours but the patient should continue to instill 5 drops of Hydrocortisone and Acetic Acid Otic Solution 3 or 4 times daily thereafter, for as long as indicated. In pediatric patients, 3 to 4 drops may be sufficient due to the smaller capacity of the ear canal.

#### HOW SUPPLIED

Hydrocortisone and Acetic Acid Otic Solution, USP, containing hydrocortisone (1%) and acetic acid (2%), is available in 10 mL, measured-drop, safety-tip plastic bottles.

#### STORAGE

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Keep container tightly closed.

Manufactured for:

**QUALITEST PHARMACEUTICALS**

Huntsville, AL 35811

8180670

R11/07-R1

#### PRINCIPAL DISPLAY PANEL

